Remarks

Status of the Application

Claims 1-10 are pending in the application. Claims 1-4 and 7-10 stand rejected under 35 USC §102(b), 35 USC §103(a), or both in alternative. Claims 5-6 are withdrawn from consideration. In addition, claims 4 and 8 stand objected under 35 USC §112.

Claim Amendments

To advance the prosecution along with this request for continued examination, claims 1, 4, 7, 8, 9 are amended. Claim 11 is added as a result of amendment on claim 4.

Arguments are arranged in the same sequential order as set forth in the final-office action mailed on February 21, 2008.

Election of Species

To advance the prosecution of this application, the Applicant confirms the election of claims 1-4 and 7-10 for prosecution. Claims 5-6 are canceled.

Claim Rejections – 35 USC § 112

Claims 4 and 8 were rejected under 35 USC § 112, second paragraph, as being indefinite.

Claim 4 is amended to include only one of the ranges, namely "1:0.1 to 1:10". A new claim 11 is added to claim the range of 1:0.5 to 1:2. No new matter is introduced by the amendments.

Applicant also amended claim 8 to remove the word "about" so the amended claim 8 points to the method that the combination drug are administered "at the same time".

With the aforementioned amendments, applicant respectfully request that the rejections on claim 4 and claim 8 to be withdrawn.

Claim Rejections – 35 USC §102

Claims 1-3, 7, 9-10 were rejected under 35 USC 102(b) as being anticipated by Patemiti et al (WO9805331).

As agreed by the Examiner, the pharmaceutical composition disclosed by Patemiti et al comprises a PPARgamma agonist. The Applicant amended claim 1 using the closed transitional phrase "consisting of" to specifically point out the invention and excluding any non-recited elements.

With the aforementioned amendments, claim 1 is patentably distinct from Patemiti et al. Claims 2-3, 7, 9-10 are dependent upon claim 1 and are therefore also patentably distinct from Patemiti et al. Allowance of amended claims are respectfully requested.

Claim Rejections – 35 USC § 103

Claim 4 was rejected under 35 USC 103 (a) as being unpatentable over Patemiti et al.

As agreed by the Examiner, the pharmaceutical composition disclosed by Patemiti et al comprises a PPARgamma agonist. Applicant amended claim 1

using the closed transitional phrase "consisting of" to specifically point out the invention and excluding any non-recited elements.

Amended claim 4 is now dependent upon amended claim 1 and therefore is patentably distinct from Patemiti et al. Patemiti et al does not teach that the pharmaceutical composition without the PPARgamma agonist could be effective. Patemiti et al actually indicates that the instant invention was not obvious at the time the invention was made.

With the aforementioned amendments, allowance of claim 4 is respectfully requested.

Claim 8 was rejected under 35 USC 103(a) as being unpatentable over Barelli at al (US 5922769) in view of Ko et al.

As provided in previous responses and agreed by the Examiner, the instant invention is directed to the unexpected synergistic effect between metformin and gemfibrozil in reducing plasma glucose concentrations. To clearly point out the invention, claim 8 is now dependent upon amended claim 1 that is now amended to use "consisting of" to exclude any non-recited elements.

Claim 8 is, in addition, amended to delete the word "about".

The amendments should put claim 8 in allowable condition. The rejection on claim 8 is respectfully requested to be withdrawn.

Interview Summary

A telephone interview after final rejection was kindly permitted by the Examiner and conducted on March 18, 2008. In the interview summary mailed on March 28, 2008, the Examiner maintained the rejections set forth in the final office action dated on February 21, 2008. In addition, the Examiner cited a new reference, Weintraub et al (1998), to indicate that it is obvious to combine individual compositions. The Examiner also noted the English abstract of a French patent FR 2796940.

Although not specifically stated by the Examiner in the interview summary, the Applicant assumes that the Examiner is using the ***Weintraub et al*** and the ***Weintraub et al*** in view of ***FR 2796940*** for rejections on claim 1 as being obvious under 35 USC 103(a). Following arguments are based on the aforementioned assumption.

The Applicant respectfully points out that type IV HLP and non-diabetic glucose intolerance are two very distinct disorders. They both may have increase PPLp as Weintraub et al demonstrated. However, the etiology, pathogenesis and pathophysiology of the two disorders are very different, as such that the treatments are also very different. In fact, Weintraub et al specifically teaches that gemfibrozil be used for patients with type IV HLP and metformin for patients with non-diabetic subject who were glucose intolerant (Weintraub, et al, page S72, last two lines in left column to first line in right column, and Table 1 and Table 2). Furthermore, Weintraub et al concluded that "This situation (increase PPLp) can be dramatically improved by fibric acid derivatives in the case of

hypertriglycemia (type IV HLP) and isolated low HDL-C and by metformin in the case of obese with glucose tolerance" (page S74, last 4 lines in the left column). Even with the possession of both gemfibrozil and metformin, Weintraub et al did not combine both drugs in any single patient or group of patients. Instead, Weintraub et al teaches using one drug to treat one specific disorder. It clearly indicates that it would not be obvious to those skilled in the art to combine the two drugs at the time the invention was made.

In addition, Weitraub et al teaches that gemfibrozil [Applicant's *Note: Weintraub et al seemed using "gemfibrizil" and "gemfibrozil" interchangeably*] and metformin should be used differently, such as, "**6 weeks** of gemfibrozil 1200 mg/day treatment in the case of **type IV patients**, ... and **3 months** of 850 g metformin twice a day in the case of the **non-diabetic glucose intolerant subjects**" (page S72, second paragraph, right column). The fact that Weintraub et al used such different treatment regimens on different patients with the two drugs teaches away from the combination of the two drugs. It also indicates that it would not be obvious to those skilled in the art to combine the two drugs to treat a same patient at the time the invention was made. Also, Wientraub et al stated that "gemfibrozil therapy caused the RP response in these patients to be more like normal" (page S73, first paragraph, right column, line 7 to 9). It further teaches away from combing any other drug with gemfibrozil as there would be no additional benefit for the patients by doing so.

In conclusion, Weintraub et al, teaches that two drugs such as gemfibrizil and metformin were to be used to treat different patients with different disorders

and with completely different treatment regimens, and there was no rationale to combine gemfibrozil with other drugs since gemfibrozil itself already normalized RP response. Based on these teachings, it would not be obvious to those skilled in the art, such as Weintraub et al, to combine the two drugs to treat a same patient.

Regarding FR 2796940, it was known that metformin can be used to treat symptoms of diabetes mellitus including hyperglycemia (i.e., high plasma glucose level). FR 2796940 did not teach that metformin can be combined with other drug or drugs. FR 2796940 alone or Weintraub et al in view of FR 2796940 would not make the instant invention obvious at the time the invention was made.

Conclusion

In view of the foregoing, allowance of the pending claims is respectfully requested.

Respectfully submitted,

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